

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: WAVE 3 CASES	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**REPLY IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE THE OPINIONS OF DR. SHELBY THAMES**

In further support of their Motion to exclude certain opinions and testimony of Defendants' expert, Dr. Shelby Thames ("Dr. Thames"), Plaintiffs state as follows:

I. Notice of Adoption

Plaintiffs hereby adopt and incorporate by reference the *Daubert* Reply filed to exclude or limit Dr. Thames' opinions for Ethicon Wave 2, Dkt. 2621. Plaintiffs respectfully request that the Court exclude Dr. Thames testimony, for the reasons expressed in the adopted Wave 2 motion, memorandum and reply, as well as the additional arguments detailed in Plaintiffs' Wave 3 adoption and those explained below.

II. Reply to Additional Arguments

Ethicon's Response to Plaintiffs' Motion makes reference to the findings of a Second Supplemental Report from Dr. Thames that was served after Plaintiffs filed their *Daubert* Motion for Wave 3. Indeed, this Second Supplemental Report was served on September 28, 2016¹—which was not only after when *Daubert* motions were to be filed (September 19, 2016), but it

¹ Ex. A, Supplemental Report of Dr. Thames (September 28, 2016).

was also after the close of discovery (August 30, 2016) and after the deadline to serve defense expert reports (August 2, 2016).² *Wave 3 Docket Control Order* [Doc. No. 1824] at 1. As such, Plaintiffs have never had the opportunity to move to exclude those opinions for relevance and reliability, and any reference to this second supplemental report should not be considered by the Court in making its *Daubert* determination here.³ Def. Brief at 3-6.

1. Dr. Thames' opinions based on his destructive testing of explanted mesh are unreliable.

Dr. Thames' opinions expressed in his general report about the presence of extrusion lines and clear or colored flakes on explanted meshes after they were cleaned by him need to be excluded.⁴ Dr. Thames has never subjected his cleaning protocol for explanted meshes to a proper control that would determine if it is destroying evidence of surface oxidation. Indeed, Ethicon does not dispute this fact in its brief—instead, it argues that the peer reviewed literature (stating that abrasive cleaning of Prolene destroys surface oxidation) does not exactly replicate Dr. Thames' cleaning protocol—so it must be discounted entirely. Def. Brief at 2, FN1. But this is not the case.

The court's focus in a *Daubert* inquiry should be solely on experts' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Here, not only has Dr. Thames not tested *if* his cleaning protocol destroys evidence of oxidation, but the literature warns against using abrasive methods to clean explanted Prolene—and—Dr. Thames ignored those warnings.

Dr. Thames only *assumed* that his protocol did not destroy evidence of oxidation—as such, he should be prevented from offering any opinions about extrusion lines or clear or colored flakes on any explanted meshes that he cleaned—including the ones described in his general

² Plaintiffs and Defense agreed to extend this deadline until August 8, 2016.

³ Plaintiffs have a Motion to Strike this Second Supplement for Wave 3 that is currently pending before the Court.

⁴ Ex. B, Thames Wave 3 report at 102-122.

report.⁵ Those opinions are the tainted result of an unscientific and untested cleaning protocol that is destroying the very evidence Dr. Thames was supposedly looking for—and they should not be allowed at trial.

2. Ethicon has not provided the Court with any argument that would allow Dr. Thames to testify in at least four areas.

As explained in Plaintiffs' Wave 2 Reply to their Motion to Exclude the Opinions and Testimony of Dr. Thames, there are four areas where Ethicon does not dispute that Dr. Thames' opinions should be excluded.

- Ethicon does not dispute that Dr. Thames should be prevented from testifying that Prolene does not degrade inside the body.
- Ethicon does not dispute that Dr. Thames should be prevented from testifying that no molecular weight changes were recorded internally by Ethicon, or by Plaintiffs' experts.
- Ethicon does not dispute that Dr. Thames' dog study-based 'toughness' opinions have no statistical significance, and therefore, cannot be applied to all of the women implanted with Prolene-based meshes.
- Ethicon does not dispute that if Dr. Thames' cleaning protocol actually destroys evidence of oxidation on Plaintiffs' meshes then his opinions on the presence of extrusion lines and colored flakes have absolutely no support.

Moreover, this Court has already ruled that Dr. Thames cannot misstate the findings of the internal dog study—and tell a jury that no molecular weight loss was recorded. (*Daubert* Motion re: Shelby Thames, Ph.D.) (S.D. W. Va. Sept. 2, 2016) [ECF No. 2723]. But it is equally important to recognize that Dr. Thames' toughness opinions also rest on a foundational opinion that Prolene does not degrade *in vivo*. As Dr. Thames explained:

Q. Let me ask this question, then. In the dog study, that was a study done by Burkley.

A. Yes, sir.

Q. B-U-R-K-L-E-Y. Did Dr. Burkley conclude that oxidative degradation took place?

A. He indicated that there might be some oxidative degradation, and he was wrong. **Because if there had been, you would not see a [stress strain] curve**

⁵ Ex. B, Thames Wave 3 report at 102-122.

like this. It's impossible to have oxidative degradation and have that curve of physical properties and **no loss in molecular weight**.

Q. Okay.

A. They go together. It's like being married and having your first child. You know, carbonyl group formation, **loss in molecular weight** and physical properties, they all go together.⁶

As such, and since Ethicon does not dispute its exclusion and the Court has previously excluded his opinion that the internal dog study showed no losses in molecular weight, Dr. Thames' toughness opinions must also be excluded—not only because they have no statistical validity, but also because they cannot stand if Dr. Thames is being prevented from stating that Prolene does not lose molecular weight inside the body.

3. Ethicon offers no reason why Dr. Thames' after-the-fact control experiment has scientific reliability.

Plaintiffs' Motion complains that Dr. Thames' after-the-fact control experiment has no scientific reliability, and that it is not related in any way to how these meshes are actually oxidized inside the human body. Ethicon has no answer to alleviate or counter these complaints. Instead, Ethicon agrees with the Plaintiffs' concerns over this testing and states that:

“Dr. Thames will not opine at trial that the test proves that his cleaning protocol does not or cannot eliminate evidence of oxidation on Prolene. Rather, Dr. Thames will testify that he has conducted a test on a Prolene mesh using certain elements of his cleaning protocol, and that this test showed no reduction in oxidation on that mesh.”

But this explanation is an admission that Dr. Thames' control experiment is irrelevant and useless to the trier of fact. Worse, even though Ethicon admits that this testing shows nothing of value, Dr. Thames wants to tell a jury that his after-the-fact experiment showed that his cleaning

⁶ Ex. C, Thames Dep. at 135:21-136:12 (emphasis added).

protocol did not reduce oxidation on the mesh—which has nothing to do with if his cleaning protocol destroys evidence of oxidation. None of this can be allowed.

It is, by Ethicon's admission, irrelevant—but it is also too confusing for a jury to hear and this is exactly what the Court's gatekeeper function in the *Daubert* analysis entails—keeping out irrelevant and unreliable evidence. In addition, the testing has no statistical validity and it was incomplete at the time his report was served.

CONCLUSION

For the foregoing reasons, Dr. Thames should be limited in what he can testify about in these Wave 3 cases. No jury should ever hear any evidence that is unreliable—and Dr. Thames' *ipse dixit* and factually unsupported opinions should be precluded. Finally, all additional materials, not produced in a timely manner should be stricken and not considered at this time. Plaintiffs respectfully request their Motion be granted.

Dated: October 21, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on October 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace

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